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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,190	07/28/2003	Sau Wei Li	4-32594A	5522
1095	7590	10/05/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER GEMBEH, SHIRLEY V	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/629,190

Applicant(s)

LI ET AL.

Examiner

Shirley V. Gembah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 1-3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/24/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of claims 1-3 in the reply filed on March 05, 2007 is acknowledged.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 12/24/03 is acknowledged and has been reviewed.

***Claim Objections***

Claims 1-3 are objected to because of the following informalities: line 3 of instant claim 1, starting with transient and ending with gene should be in parenthesis and the abbreviation TRPC6 should follow so as to clarify citing TRPC6 in dependent claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith, WO 02/48342 (Applicant's submission).

Keith teaches a method of identifying agents having an effect on TRP6 expression or function wherein the method includes measuring a response and

screening compounds that may have an effect on TRPC6 (same as TRPC6) expression or function against cells in cell-based assays, for example, to identify such compounds. See page 3, lines 23-29.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith, WO 02/48342 (Applicants submission) taken with Li et al., Trends in Pharm. Sci.

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Vol. 23 (2) February 2002 in view of Clapman et al., Nature Reviews /Neuroscience 2, 2001, 307-Biol. Chem. Applicants submission.

Applicant claims a method of identifying a substance suitable for use in the treatment of a leukocyte-associated inflammatory disease which modulates the activity of a polypeptide encoded by the human transient receptor potential 6 gene, wherein the method comprises combining a candidate substance with said polypeptide and measuring the effect of the candidate substance on the activity of said polypeptide.

Keith teaches a method of identifying agents having an effect on TRPC6 expression or function wherein the method includes measuring a response and screening compounds that may have an effect on TRPC6 expression or function against cells in cell-based assays, for example, to identify such compounds. See page 3, lines 23-29.

Li et al., teach the receptor activated  $\text{Ca}^{2+}$  channel blocker SK&F 96365 inhibits calcium influx in human eosinophils (see page 65, Fig. 2). The SK&F 96365 inhibitor has been used in fluorometric and functional studies effect has been used in human eosinophils. The reference further teaches (transient receptor potential 6 gene) is present in leukocytes and further teaches, see page 68 underlining, that because  $\text{Ca}^{2+}$  influx is a common activation response in leukocytes stimulated by several inflammatory mediators, inhibitors of  $\text{Ca}^{2+}$  influx might be expected to attenuate leukocyte activation independently of the agonist hierarchy present in inflammation. Therefore, the development of inhibitors of receptor-activated  $\text{Ca}^{2+}$  influx channels could be a more effective approach for the development of anti-inflammatory drugs than a single

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mediator antagonist approach for inflammatory disease such as chronic obstructive pulmonary disease, rheumatoid arthritis, arteriosclerosis and multiple sclerosis, (see underlining page 68, rt. col.). The reference also teaches the main activation pathway of the receptor –activated  $\text{Ca}^{2+}$  is through G-protein coupled receptor.

With regard to the membrane depolarization to induce a TRPC6-mediated  $\text{Na}^+$  is taught by the reference Clapman et al., wherein current voltage is regulated. See page 303 rt. hand col. Examiner believes that absent factual evidence ion channels are membrane bound proteins that conduct ions at a rate near the diffusion limit across the plasma membrane or across the membrane of intracellular organelles (e.g., mitochondria). When an ion channel opens, the direction of movement of the permeant ions is determined solely by the transmembrane voltage and concentration gradient for the permeant ion. Sodium and calcium concentrations are much higher outside the cell than inside the cell. Thus, under normal physiological conditions when sodium or calcium channels open,  $\text{Na}^+$  or  $\text{Ca}^{2+}$  diffuse from outside to inside the cell. Therefore, one of ordinary skill in the art would be motivated to combine the prior art of record identify agents having an effect on TRPC6 expression or function and measure the response, screening compounds that may have an effect on TRP6 expression or function against cells in cell-based assays, for example, to identify such compounds as taught in the prior art.

The combine reference makes the claimed invention obvious over the prior art and one of ordinary skill in the art would have been motivated to do so because the prior art teaches the claimed invention at the time it was made.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG  
9/26/07

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER